

# Environmental Management Act

Notification Article 8.19 Environmental Management Act

To the Burgomaster and Aldermen of the Municipality of Leiden (Environmental Department)

Name of applicant:

Address:

Postal code and municipality

Telephone number:

Name of company:

Mentor Medical Systems B.V.

Nature of plant:

Production of medical aids.

Address of plant:

Einsteinweg 5  
2333 CC LEIDEN

Contact person and telephone number:

Mr. J.J.H. Smit (071) 521 50 07

Herewith give notification of a modification of the plant, which will not, or only positively, affect the environment and ask for this report to be treated as a notification in accordance with Art. 8.19 of the Environmental Management Act.

Nature of modification:

Feasibility study with respect to the automatic manufacture of the components (coverings) required for production.

(See explanatory notes.)

(Include drawings (pto))

Outline why you think that the change will not, or only positively, affect the environment:

The feasibility study is small-scale.

(See explanatory notes.)

Construction permit:

☐ applied for: .....

☐ will be applied for

☒ not applicable

(tick where appropriate)

Ondertekening:

Plaats:

datum:

13 JAN 99

handtekening:

(In te vullen door Sector milieu)  
Vergunningnummer en -datum:

Paraaf voor akkoord:

C

## Explanatory notes with notification Article 8.19

- Nature of the modification

Mentor Medical Systems B.V. obtains components for the medical aids produced in Leiden from a sister company in the United States. Because of the desire for more independence, and because of the inefficiency and thus uneconomical methodology of production at the sister company, an investigation was started into the possibilities for the (automized) manufacture of the components in Leiden.

The fabrication of the coverings necessary for our products occurred up to now by means of a manual dipping process. The (dipping) liquid used is silicones dissolved in xylene. If in the future this process is to take place in Leiden, it is the intention to automize this process. This process resembles the methodology used in the production of condoms, balloons or rubber teats. The significant difference is to be found in the dipping liquid to be used, with which there is little or no experience. In order to sensibly handle the capital lay-out, it has been decided to first carry out a feasibility study. This study will be realised with the aid of a dipping robot able to dip three moulds simultaneously into a liquid bath (see the enclosed drawing, enclosure 1).

The results of this study may provide grounds for a production-scale machine, resulting in a further expansion of the activities in Leiden. The laboratory-scale study may conveniently be fitted into the presently unused space in our building, previously the C-lab on the ground floor (see enclosed drawing, enclosure 2).

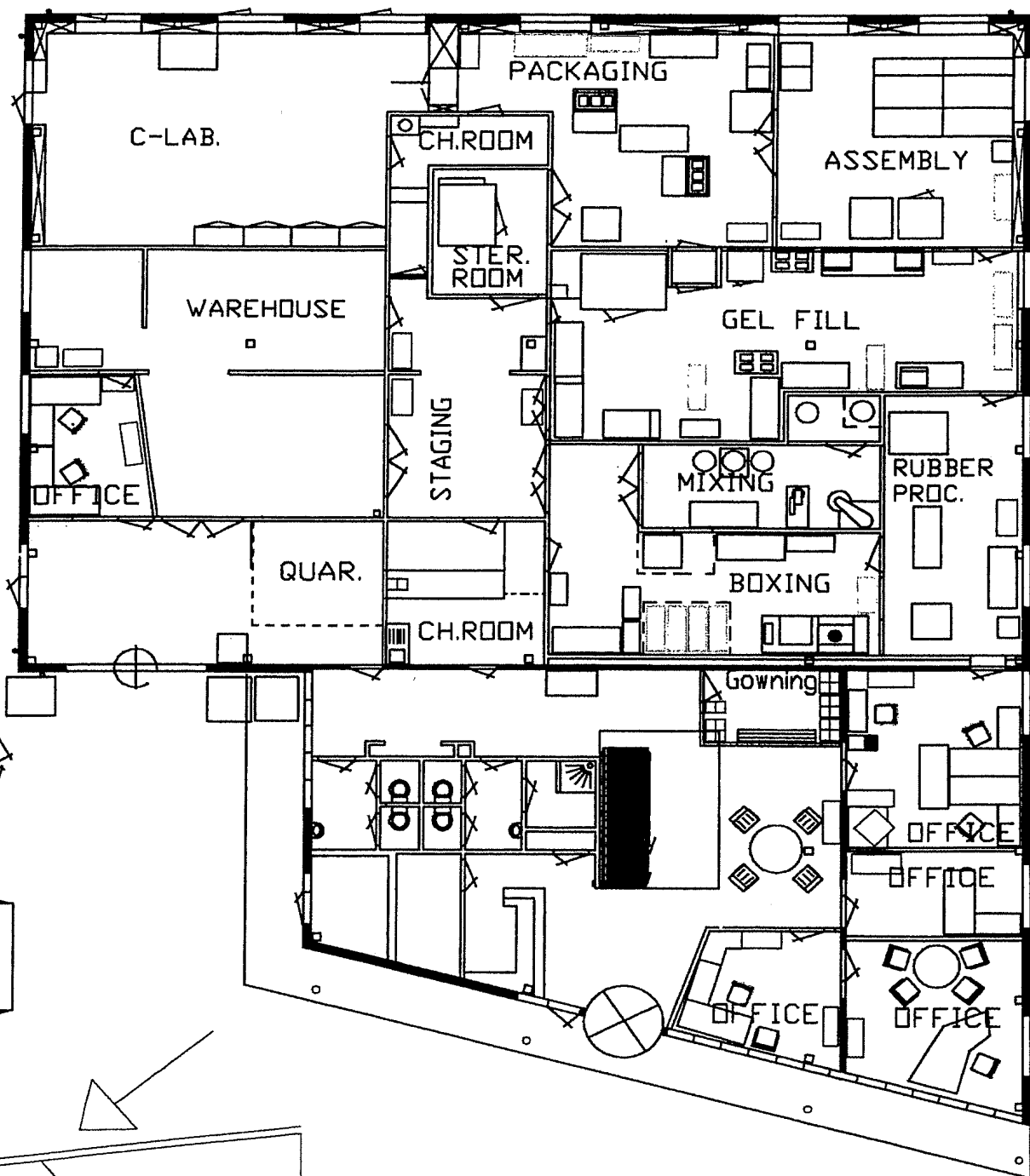
- Consequences for the environment

The reason for our thinking that this modification will have minor consequences for the environment and that therefore an application via Article 8.19 will suffice, is the fact that the feasibility study is small-scale.

Dipping of the covering occurs in three stages. Each stage takes approximately fifteen minutes, with per dipping, per mould, approximately 10 grams of xylene evaporating. After dipping three moulds three times, 90 grams of xylene will have evaporated. After evaporation of the xylene, the moulds are placed into an oven to cure the silicones in a cycle taking four hours. In view of the time required, we expect that the activity will be limited to one processing round per day. The above figures have been obtained by measuring.

We wish to emphasize again that the main object of this feasibility study is to obtain data for a possible production-scale machine. Further objectives within this feasibility study are to eliminate the inefficiency and to significantly reduce the waste material produced currently with the manual process. If the feasibility study is a success and the management of Mentor decides to purchase such a machine, the permit question will take a completely different turn. Shortage of space will then oblige us to seek additional space or to consider expansion, and with that also a different permit.





ENCLOSURE 2